Remarks

The Applicants note with appreciation the withdrawal of the obviousness-type double patenting rejection over US Patent No. 6,168,805 B1, the §112, second paragraph rejection of Claim 9 and the §102 rejection over Oshlack.

The Applicants confirm the earlier withdrawal of Claims 10 – 15 as being drawn to non-elected subject matter. The Applicants now cancel Claims 10 – 15 without prejudice and without disclaimer of the subject matter therein. The Applicants specifically reserve the right to file one or more divisional applications directed to the subject matter of those claims.

Claims 1 – 9 continue to stand provisionally rejected over claims of three co-pending applications based on non-statutory obviousness-type double patenting. The Applicants respectfully submit that, since this is a provisional rejection, it should be withdrawn and applied, if appropriate, in various other applications subsequent to issuance of this application. As a consequence, the Applicants respectfully request that this rejection be withdrawn with the proviso that it may be applied to one or more of the other applications in the event that it is appropriate and in the event that appropriate claims in those applications are otherwise in condition for allowance.

Claims 1 and 3 – 8 are rejected under 35 USC §112 as failing to comply with the written description requirement. The Applicants note with appreciation the Examiner's detailed comments in support of the rejection. The Applicants respectfully submit, however, that the claims are in full compliance with §112, first paragraph. Reasons are set forth below.

The rejection is based on a lack of adequate written description and cites various case law in support of that position. For example, the rejection states:

> A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled

> in the art to immediately envisage the product claimed from the disclosed process.

The Applicants respectfully submit that one skilled in the art, given the high level of skill in this art, could and would immediately envision the product claimed from the disclosed process. It should be noted that the inventive subject matter in Claims 1 and 3 – 8 is not the active pharmaceutical ingredient *per se*, but the controlled release dosage form. One skilled in this art, as noted above, is of very high skill, and can immediately envisage the product claimed from the disclosed process. One skilled in this art readily recognizes that there are hundreds and hundreds of active pharmaceutical ingredients that can be utilized in conjunction with the Applicants' controlled release oral dosage form.

In fact, the Applicants respectfully submit that it takes no imagination at all for one skilled in the art to recognize that hundreds of different active pharmaceutical ingredients could be utilized in conjunction with the controlled release oral dosage form. Reference to any number of hundreds of issued patents reveals that those skilled in this art often provide long lists of active pharmaceutical ingredients that run for column after column after column with specific examples. Inasmuch as those skilled in the art are well aware of such hundreds and hundreds of active pharmaceutical ingredients, it is not necessary for the Applicants to provide a list of every possible active pharmaceutical ingredient that could be utilized in conjunction with the claimed controlled release oral dosage form. It is also well acknowledged that it is not necessary for a patent applicant to repeat over and over and over that which is already known to those skilled in the art. As noted above, those skilled in this art have very high skill and well know that patents that are directed to formulations or dosage forms are capable of use in conjunction with a very wide broad array of active agents.

The rejection focuses in particular on the so-called broad term of "an active pharmaceutical ingredient." The rejection also states that "the mere fact that Applicant may have discovered one type of active pharmaceutical ingredient formed in the instant process is not sufficient to claim the entire genus." The Applicants did not discover one type of active pharmaceutical ingredient formed for use in conjunction with the claimed controlled release oral dosage form. The Applicants discovered that the claimed controlled release oral dosage form could be used in a very, very wide array of active pharmaceutical ingredients. This can readily be seen by reference to the Applicants' Specification in several locations. For example, the Applicants recite on page 3, beginning at line 9, that the method can be used "with a wide range of active pharmaceutical compounds." What this means is that the Applicants very much envisioned that the active pharmaceutical compounds that can be used in conjunction with the claimed controlled release oral dosage form is very, very broad indeed. It in no way should be limited to specific, selected examples chosen for illustration in the Specification.

Page 4 sheds further light on the fact that the Applicants envisioned a wide range of active pharmaceutical ingredients. This may be found in lines 14 and 15, which recite "the active ingredient may be any therapeutically active pharmaceutical ingredient(s) or a combination of active ingredients." Again, the Applicants respectfully submit that they indeed envisioned that "any" active pharmaceutical ingredient could be employed in conjunction with the claimed controlled release oral dosage form. Moreover, the Applicants envisioned combinations of those active ingredients.

The fact that the Applicants were in possession of the subject matter of Claims 1 and 3 – 8 with respect to the claimed "active pharmaceutical ingredient" is further illustrated on page 4 of the Applicants' Specification, again on line 15, which provides a list of more than a dozen

"preferred" active ingredients. This plainly states to those skilled in the art that the Applicants envisioned a wide range of active pharmaceutical ingredients that could be used in conjunction with the claimed oral dosage form beyond the specific examples recited in the Specification. The Applicants then went on to list more than a dozen specific active ingredients that could be used and also note that those active ingredients could include salts or mixtures thereof. The Applicants therefore respectfully submit that it would be in error to take the position that "the mere fact that Applicant may have discovered one type of active pharmaceutical ingredient formed in the instant process is not sufficient to claim the entire genus." The Applicants did not discover one type of active pharmaceutical ingredient formed in the instant process. What the Applicants discovered was a controlled release oral dosage form that can include any number of a wide range of active pharmaceutical ingredients. That is what the Applicants invented, not a specific list of active pharmaceutical ingredients.

The rejection then quotes from *Eli Lilly*, which apparently concludes with the statement that "the disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."" There can be no doubt in this case that the Applicants did not invent one species. Again, the Applicants invented a controlled release oral dosage form that may used in conjunction with a "wide range" or "any" pharmaceutical ingredient. Moreover, the Applicants provided over a dozen specific "preferred" examples. This in no way constitutes one species and, as such, *Eli Lilly* is factually inapposite. Said differently, the Applicants chose in their Specification to list a dozen or so preferred active agents and provided an example that includes oxycodone as a representative active ingredient. However, they did not believe that their invention was directed to oxycodone as a single species. That was merely a

representative example. What the Applicants envisioned was that a "wide range" or "any" therapeutically active pharmaceutical ingredient could be used in conjunction with the claimed controlled release oral dosage form. The actual active agent itself is incidental to the claimed controlled release oral dosage form. Nonetheless, the Applicants envisioned such a "wide range" or "any" active pharmaceutical ingredient in their claimed controlled release oral dosage form.

The Applicants respectfully submit that one skilled in the art could instantly, upon reading the Applicants' Claims 1 and 3 – 8, particularly when taken in conjunction with their Specification, and realize that the essence of the Applicants' inventive subject matter is directed to a controlled release oral dosage form that contains a wide range of or any active pharmaceutical ingredient. Withdrawal of the rejection is respectfully requested.

The Applicants have also added new Claim 16, which recites that the active pharmaceutical ingredient is an opioid. Support may be found in the Applicants' Specification on page 4 at line 15. Entry into the Official File, consideration on the merits and allowance is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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